

Applicants: David Stern, et al.

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**REMARKS**

Claims 42-69 are pending and under examination in the subject application. Applicants have herein amended claims 57 and 58 and added new claim 70. Support for amended claims 57 and 58 can be found in the specification at, *inter alia*, page 26, lines 24-29. Support for new claim 70 can be found in the specification at, *inter alia*, page 26, lines 24-27. Applicants maintain that the amendments to claims 57 and 58 and the addition of new claim 70 raise no issue of new matter. Accordingly, upon entry of this Amendment, claims 42-70 will be pending in the subject application.

**Restriction/Election**

In the November 9, 2005 Office Action, the Examiner restricted pending claims 42-69 to one of the following allegedly distinct inventions under 35 U.S.C. §121 as follows:

- I. Claims 42-45 and 55-69, drawn to a method for preventing and/or treating a disease involving  $\beta$ -sheet fibril formation, other than Alzheimer's disease, in a subject which comprises administering to the subject a binding-inhibiting amount of a compound capable of inhibiting binding of  $\beta$ -sheet fibril to RAGE, wherein the compound is sRAGE or a fragment thereof;

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- II. Claims 42, 24, 53 and 55-69, drawn to a method for preventing and/or treating a disease involving  $\beta$ -sheet fibril formation, other than Alzheimer's disease, in a subject which comprises administering to the subject a binding-inhibiting amount of a compound capable of inhibiting binding of  $\beta$ -sheet fibril to RAGE, wherein the compound comprises an antibody or a portion thereof;
- III. Claims 42, 47-52 and 55-69, drawn to a method for preventing and/or treating a disease involving  $\beta$ -sheet fibril formation, other than Alzheimer's disease, in a subject which comprises administering to the subject a binding-inhibiting amount of a compound capable of inhibiting binding of  $\beta$ -sheet fibril to RAGE, wherein the compound is an anti-RAGE antibody or a portion thereof;
- IV. Claims 42, 54 and 55-69, drawn to a method for preventing and/or treating a disease involving  $\beta$ -sheet fibril formation, other than Alzheimer's disease, in a subject which comprises administering to the subject a binding-inhibiting amount of a compound capable of inhibiting binding of  $\beta$ -sheet fibril to RAGE, wherein the compound comprises a peptide;
- V. Claims 42, 54 and 55-69, drawn to a method for

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preventing and/or treating a disease involving  $\beta$ -sheet fibril formation, other than Alzheimer's disease, in a subject which comprises administering to the subject a binding-inhibiting amount of a compound capable of inhibiting binding of  $\beta$ -sheet fibril to RAGE, wherein the compound comprises a peptidomimetic;

VI. Claims 42, 54 and 55-69, drawn to a method for preventing and/or treating a disease involving  $\beta$ -sheet fibril formation, other than Alzheimer's disease, in a subject which comprises administering to the subject a binding-inhibiting amount of a compound capable of inhibiting binding of  $\beta$ -sheet fibril to RAGE, wherein the compound comprises a nucleic acid; and

VII. Claims 42, 54 and 55-69, drawn to a method for preventing and/or treating a disease involving  $\beta$ -sheet fibril formation, other than Alzheimer's disease, in a subject which comprises administering to the subject a binding-inhibiting amount of a compound capable of inhibiting binding of  $\beta$ -sheet fibril to RAGE, wherein the compound comprises an organic compound with a molecular weight of less than 500 daltons.

In addition, the Examiner stated that election of one of Groups I-VII would require the election of one of the following single disclosed species for prosecution with

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respect to the  $\beta$ -sheet fibril group if no generic claims, i.e. claims 55-57, are finally held to be allowable:

- a. Amyloid fibril;
- b. Prion-derived fibril;
- c. Amyloid- $\beta$  peptide;
- d. Amylin;
- e. Amyloid A;
- f. Prion-derived peptide;
- g. Transthyretin;
- h. Cystatin C;
- i. Gelsolin; and
- j. Peptide capable of forming amyloid.

In addition, the Examiner stated that election of one of Groups I-VII would require the election of one of the following single disclosed species for prosecution with respect to the amyloid- $\beta$  peptide group if no generic claim, i.e. claim 58, is finally held to be allowable:

- a. A $\beta$  (1-39);

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- b. A $\beta$  (1-40);
- c. A $\beta$  (1-42); and
- d. A $\beta$  (1-40) Dutch variant.

In addition, the Examiner stated that election of one of Groups I-VII would require the election of one of the following single disclosed species for prosecution with respect to the disease group if no generic claims, i.e. claims 64-69, are finally held to be allowable:

- a. Diabetes;
- b. Hyperlipidemic atherosclerosis;
- c. Neuropathy;
- d. Nephropathy;
- e. Amyloidosis; and
- f. Wound associated with diabetes.

In response, applicants hereby elect, with traverse, the invention identified by the Examiner as Group I, claims 42-45 and 55-69. Applicants also understand Group I includes new claim 70, which merely provides subject matter previously recited in claim 57. Applicants also elect (i) the species corresponding to a peptide capable of forming

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amyloid with respect to the  $\beta$ -sheet fibril group, (ii) the species corresponding to A $\beta$  (1-42) with respect to the amyloid- $\beta$  peptide group and (iii) the species corresponding to amyloidosis with respect to the disease group, with traverse, for prosecution at this time. Applicants note that claims 42-45, 55 and 59-70 read on elected species (i), claims 42-45 and 57-69 read on elected species (ii) and claims 42-45, 55-63, 68 and 70 read on elected species (iii).

However, applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement.

Under 35 U.S.C. §121, restriction may be required if two or more independent and distinct inventions are claimed in one application. Under M.P.E.P. §803, the Examiner must examine the application on the merits if examination can be made without serious burden, even if the application would include claims to distinct or independent inventions. That is, there are two criteria for a proper requirement for restriction: (1) the invention must be independent and distinct, and (2) there must be a serious burden on the Examiner if restriction were not required.

Applicants respectfully submit that there would not be a serious burden on the Examiner if restriction were not required, because a search of the prior art relevant to the claims of Group I would provide the relevant prior art for Groups II-VII. Since there is no burden on the Examiner to examine Groups I-VII together in the same application, the

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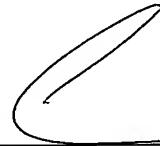
Examiner must examine the entire application on the merits.

In view of the foregoing, applicants maintain that restriction is not proper under 35 U.S.C. §121, and respectfully request that the Examiner reconsider and withdraw the requirement for restriction.

If a telephone interview would be of assistance in advancing the prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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12/9/02 Alan J. Morrison Reg. No. 37,399	Date